K132357

Endoscopy
Smith & Nephew, Inc.
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We are **smith&nephew**

510(k) Summary

Date Prepared: October 21, 2013

Submitter Information	Contact Information
Smith & Nephew, Inc. 150 Minuteman Road Andover, MA 01810	Melody Bi Senior Regulatory Affairs Specialist Phone: (508) 337-4035 Fax: (978) 749-1443

OCT 30 2013

Device Name (Unmodified)	
Trade or proprietary name	Smith & Nephew ULTRATAPE
Common or usual name	Non-absorbable Surgical Suture
Classification name	Polyethylene Non-absorbable Surgical Suture

Legally Marketed Predicate Device

The Smith & Nephew ULTRATAPE surgical suture is substantially equivalent in intended use and Fundamental Scientific Technology to the following legally marketed devices in commercial distribution:

K101377 **Smith & Nephew ULTRABRAID II Suture**
(Cleared on April 8, 2011)

K041216 **Smith & Nephew ULTRABRAID Suture**
(Cleared on June 7, 2004)

Device Description

Smith & Nephew ULTRATAPE is a non-absorbable, sterile, synthetic surgical suture composed of UHMW (Ultra High Molecular Weight) polyethylene, offered braided, in both blue and a co-braid of blue/ white. ULTRATAPE is flat in shape, and has a width of 2mm, meeting USP tensile strength requirement for size #2 surgical suture. ULTRATAPE does not comply with USP size classifications. When used with various anchoring implants in orthopedic procedures, it secures and holds the reattached tendon to bone.

Intended Use

Smith & Nephew ULTRATAPE is indicated for use in approximation and/or ligation of soft tissues, including allograft tissue for orthopedic surgeries.

Technological Characteristics

Smith & Nephew ULTRATAPE is substantially equivalent to its predicate devices, ULTRABRAID suture (K041216) and ULTRABRAID II suture (K101377) based on the same intended use, and the following commonalities in technological characteristics:

- Same UHMWPE material is used in the manufacture of proposed and predicate devices.
- Both proposed and predicates have braided configurations.
- The test method used to confirm the performance specifications of Knot Tensile Strength for both the proposed and predicate devices were conducted in accordance with USP requirements.

The differences between ULTRATAPE and its predicate devices include that ULTRATAPE has a different braiding configuration, which provides a flat, 2mm wide suture. ULTRATAPE does not comply with USP size classifications. These differences do not raise new questions of safety or efficacy. Therefore, ULTRATAPE is as safe and effective as its currently marketed predicate devices.

Performance Data

Mechanical testing data for Knot Tensile Strength according to USP standard for non-absorbable, #2 size surgical suture demonstrates the device has met the performance specifications and therefore, is substantially equivalent to the currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 30, 2013

Smith & Nephew Incorporated
Ms. Melody Bi
Senior Regulatory Affairs Specialist
150 Minuteman Road
Andover, Massachusetts 01810

Re: K132357
Trade/Device Name: Smith & Nephew ULTRATAPE
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable poly (ethylene terephthalate) surgical suture
Regulatory Class: Class II
Product Code: GAT
Dated: September 25, 2013
Received: October 2, 2013

Dear Ms. Bi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K132357

Device Name
Smith & Nephew ULTRATAPE

Indications for Use *(Describe)*
Smith & Nephew ULTRATAPE is indicated for use in approximation and/or ligation of soft tissues, including allograft tissue for orthopedic surgeries.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

David Krause -S